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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,583	09/09/2003	Jae-Gahb Park	DE-1504	7790

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EXAMINER

SALMON, KATHERINE D

ART UNIT PAPER NUMBER

1634

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/659,583

Applicant(s)

PARK ET AL.

Examiner

Katherine Salmon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 7-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/25/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (Claims 1-6) in the reply filed on 6/16/2006 is acknowledged.
2. Claims 7-20 are withdrawn.
3. An action on the merits of Claims 1-6 is set forth below.

Priority

4. Priority to foreign application Republic of Korea 2003-0000987 (01/08/2003) under 35 U.S.C. 119(a)-(d) is not granted because a translation of the foreign application has not been provided. Therefore the filing date of the US application 09/09/2003 will be used.

Drawings

5. The drawings are objected to because Figure 3 is too dark to read, it is unclear the analysis result. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered

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and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Kim et al. (Clinical Cancer Research August 1, 2003 Vol 9 p. 2920).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15

It is noted that the authorship of the Kim et al. reference is distinct from the inventorship of the instant application and that this rejection may be overcome by the filing of a 132 Katz-type declaration.

With regard to Claim 1, Kim et al. teaches a Beta catenin microarray which detects beta catenin mutations (mutational hotspots) (Abstract). With regard to Claim 2, Kim et al. teaches the microarray is comprised of 11 codons: 29, 31, 32, 33, 34, 35, 37,

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38, 41, 45, and 48 (Abstract). With regard to Claim 3, Kim et al. teaches a microarray comprising 9 missense mutations, 1 in-frame deletion and 1 wild type for each codon (p. 2921 1st column last paragraph).

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter in which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph). With regard to Claims 4-6, Kim et al. teaches a microarray comprising 9 missense mutations, 1 in-frame deletion and 1 wild type for each codon (p. 2921 1st column last paragraph). Kim et al. teaches oligonucleotides attached to the array were 21-bp long and the mismatch sequence was located in the middle of oligonucleotides (after 10th base sequence) (p. 2921 1st column 2nd full paragraph). Therefore Kim et al. teaches the sequences as claimed in the instant claims.

7. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5,474,796 December 12, 1995).

Brennan teaches an array (abstract). With regard to Claims 1-3, Brennan teaches an array which contains oligonucleotides with 10 nucleotides each (Column 9, lines 49-50). Brennan teaches the total array represents every possible permutation of

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the 10-mer oligonucleotide (Column 9, lines 53-55). The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *in re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *in re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111). The claims are given the broadest reasonable interpretation consistent with the indefinite claim language and specification in which codons, missense mutations, inframe deletions, and wild types can be of any length. Therefore the codons can be 10 mer fragments, which are encompassed by the microarray taught by Brennan. The in-frame deletions, missense mutations, and wild types of these codons would be variations of 10 mer fragments also encompassed by the teaching of Brennan, which teaches all possible permutations of the 10-mer oligonucleotide. Further, with regard to Claim 1 the preamble for detecting beta catenin mutations is not given any patentable weight; any array with a plurality of probes drawn to beta catenin mutations could be used to detect beta catenin mutations.

8. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by El-Rifai et al. (International Journal of Cancer 2001 Vol. 93 p. 832).

With regard to Claim 1, El-Rifai et al. teaches a cDNA array comprised of oligonucleotides (Abstract). El-Rifai et al. teaches an array comprising genes such as beta catenin (Abstract). El-Rifai et al. teaches using the array to detect expression of beta catenin, therefore detecting mutations of the beta catenin gene (Abstract).

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Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Katherine Salmon
Examiner
Art Unit 1634


BJ FORMAN, PH.D.
PRIMARY EXAMINER